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Emtricitabine/Tenofovir disoproxil Krka d.d. (*emtricitabine / tenofovir disoproxil)*

An overview of Emtricitabine/Tenofovir disoproxil Krka d.d. and why it is authorised in the EU

What is Emtricitabine/Tenofovir disoproxil Krka d.d. and what is it used for?

Emtricitabine/Tenofovir disoproxil Krka d.d. is an HIV medicine that is used in combination with at least one other HIV medicine to treat adults infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS). In addition, it may be used in adolescents who are resistant to first-line treatments or who cannot take them because of side effects.

Emtricitabine/Tenofovir disoproxil Krka d.d contains two active substances, emtricitabine and tenofovir disoproxil. It is a 'generic medicine'. This means that it contains the same active substances and works in the same way as a 'reference medicine' already authorised in the EU called Truvada. For more information on generic medicines, see the question-and-answer document here.

How is Emtricitabine/Tenofovir disoproxil Krka d.d. used?

Emtricitabine/Tenofovir disoproxil Krka d.d. can only be obtained with a prescription and treatment should be started by a doctor who has experience in the management of HIV infection.

Emtricitabine/Tenofovir disoproxil Krka d.d. is available as tablets (200 mg emtricitabine and 245 mg tenofovir disoproxil). The recommended dose is one tablet once a day, preferably taken with food. If patients need to stop taking emtricitabine or tenofovir, or need to take different doses, they will need to take medicines containing emtricitabine or tenofovir disoproxil separately.

For more informationabout using Emtricitabine/Tenofovir disoproxil Krka d.d., see the package leaflet or contact your doctor or pharmacist.

How does Emtricitabine/Tenofovir disoproxil Krka d.d. work?

Emtricitabine/Tenofovir disoproxil Krka d.d. contains two active substances: emtricitabine, which is a nucleoside reverse transcriptase inhibitor; and tenofovir disoproxil, which is a 'prodrug' of tenofovir.

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This means that it is converted into tenofovir in the body. Tenofovir is a nucleotide reverse transcriptase inhibitor. Both emtricitabine and tenofovir work in similar ways by blocking the activity of reverse transcriptase, an enzyme produced by HIV that allows it to reproduce itself in the cells it has infected.

Emtricitabine/Tenofovir disoproxil Krka d.d., taken in combination with at least one other antiviral medicine, reduces the amount of HIV in the blood and keeps it at a low level. Emtricitabine/Tenofovir disoproxil Krka d.d. does not cure HIV infection or AIDS, but it holds off the damage to the immune system and the development of infections and diseases associated with AIDS.

How has Emtricitabine/Tenofovir disoproxil Krka d.d. been studied?

Studies on the benefits and risks of the active substances in the authorised use have already been carried out with the reference medicine, Truvada, and do not need to be repeated for Emtricitabine/Tenofovir disoproxil Krka d.d.

As for every medicine, the company provided studies on the quality of Emtricitabine/Tenofovir disoproxil Krka d.d. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substances in the body and are therefore expected to have the same effect.

What are the benefits and risks of Emtricitabine/Tenofovir disoproxil Krka d.d.?

Because Emtricitabine/Tenofovir disoproxil Krka d.d. is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Emtricitabine/Tenofovir disoproxil Krka d.d. authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Emtricitabine/Tenofovir disoproxil Krka d.d. has been shown to have comparable quality and to be bioequivalent to Truvada. Therefore, the Agency's view was that, as for Truvada, the benefit of Emtricitabine/Tenofovir disoproxil Krka d.d. outweighs the identified risk and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Emtricitabine/Tenofovir disoproxil Krka d.d.?

The company that markets Emtricitabine/Tenofovir disoproxil Krka d.d. will provide an information pack to doctors which covers the potential harmful effects of Emtricitabine/Tenofovir disoproxil Krka d.d. on kidney function in adults and children.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Emtricitabine/Tenofovir disoproxil Krka d.d. have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Emtricitabine/Tenofovir disoproxil Krka d.d. are continuously monitored. Side effects reported with Emtricitabine/Tenofovir disoproxil Krka are carefully evaluated and any necessary action taken to protect patients.

Other information about Emtricitabine/Tenofovir disoproxil Krka d.d.

The European Commission granted a marketing authorisation valid throughout the EU for Emtricitabine/Tenofovir disoproxil Krka d.d. on 28 April 2017.

Further information on Emtricitabine/Tenofovir disoproxil Krka d.d. can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/emtricitabinetenofovir-disoproxil-krka-dd. Information on the reference medicine can also be found on the Agency's website.

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